SUPPORTING STATEMENT
0910-0132
AFFIRMATION OF GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS

A. JUSTIFICATION

(1) Section 201(s) (copy attached) of the Federal Food, Drug, and Cosmetic Act (the Act) defines a GRAS substance as an exception from the legal definition of a food additive. This section defines a substance as GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food.

Section 409(a) (copy attached)of the Federal Food, Drug, and Cosmetic Act provides that a food additive will be considered unsafe unless it's intended use conforms to the terms of an exemption or conforms to a regulation issued under Section 409.

Section 701 (copy attached) of the Federal Food, Drug, and Cosmetic Act sets forth authority to issue regulations for the efficient enforcement of the Act.

Section 201(s) of the Act does not define what is meant by "scientific procedures" or "common use in food," nor does it specify the conditions under which the substance is to be evaluated as GRAS. To implement the GRAS provisions of Section 201(s), procedural regulations have been issued under Part 170 of 21 CFR. The procedural regulations are designed to delineate and specify, with particularity, eligibility for classification as GRAS (21 CFR 170.30; copy attached), and to set forth the information which must be submitted to FDA to gain agency concurrence that a substance is GRAS. The regulations add no substantive requirements to the law, but attempt to explain the requirements for classification as GRAS. More specifically, the procedural regulations in 21 CFR 170.35(c)(1) provide a standard format for submissions of petitions.

This is a request for OMB approval of the information collection requirements in the Petitions for Affirmation of Generally Recognized As Safe (GRAS) substances as follows:

21 CFR 170.35(c)(1) Reporting -
Specifies content of petition which establishes that GRAS criteria has been met.

2. GRAS petitions are reviewed by FDA scientific personnel to ascertain if the available data establish that the intended use is GRAS based upon either a history of the safe use of the ingredient or (in the case of a new ingredient) upon safety data. Because section 201(s) permits non-FDA persons to determine that a substance is GRAS, the GRAS petition process gives outside parties the opportunity to have their independent GRAS determination confirmed by FDA. Although this is a voluntary process, and there is some risk that FDA may not agree with the GRAS determination and may therefore conclude that the ingredient is an unsafe food



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additive, the GRAS petition process provides a public procedure for coordinating GRAS determinations. The process minimizes the potential for endangering public health when substances are marketed based upon unwarranted safety determinations and also minimizes the need by FDA to institute court actions.

3. The availability of computerized indexing services such as Med-Line and Tox-Line permits petitioners to search the scientific literature for safety data on new or existing food ingredients. Additionally, FDA has instituted, internally, a computerized indexing system (SIREN; Scientific Information Retrieval and Exchange Network) to locate data previously submitted to the agency.

In a Federal Register notice of March 20, 1997 (62 FR 13430), FDA published a Final Rule that would, under certain circumstances, permit the agency to accept electronic records, electronic signatures, and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper. These regulations apply to GRAS petitions submitted under 21 CFR 170.35(c)(1).

4. FDA continues to work with EPA and USDA to eliminate areas of duplicate data collection and evaluation. Memoranda of Understanding have been reached in the areas of pesticides and water treatment and agreements in other areas are expected.

FDA and EPA have duplicative data requirements for sanitizing solutions, FDA for safety evaluation under the Federal Food, Drug, and Cosmetic Act and EPA for safety evaluation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (formerly administered by FDA). As a matter of established policy and practice, EPA relies on FDA to review the food-contact uses of sanitizing solutions. EPA has agreed that after a final rule is issued by FDA, they will review the new label for registration of the subject sanitizing solution for food-contact use within the requirements of FIFRA.

In the Federal Register of December 29, 1995 (60 FR 67459), USDA/FSIS proposed amending the Federal meat and poultry regulations to harmonize and improve the efficiency of the procedures used by FSIS and FDA for reviewing and approving the use of substances in meat and poultry products. Also, in the Federal Register of December 29, 1995 (60 FR 67490), FDA proposed to amend its regulations governing the review of petitions for the approval of food and color additives and GRAS substances to provide for the joint review of such petitions by FSIS and FDA when meat or poultry product uses are proposed. By agreement between USDA and FDA, such listings would eliminate the need for a separate FSIS rulemaking to allow the use in meat and poultry products of FDA-approved substances. This agreement would be covered by a Memorandum of Understanding.

The Bureau of Alcohol, Tobacco, and Firearms (BATF) relies upon FDA regulations and opinions for safety evaluations of alcoholic beverage additives.

In a notice of November 28, 1994 (59 FR 60870), FDA announced the availability of a draft policy on its development and use of standards with respect to international harmonization of regulatory requirements and guidelines. It is the intent of this policy to increase FDA's effort to harmonize its regulatory requirements with those of foreign governments. Existing data can be utilized by FDA in evaluating a GRAS or food additive petition. Data in FDA files can be cross-referenced, data available in the scientific literature can be submitted, and data gathered from other government agencies such as EPA and USDA may be submitted in support of a GRAS or food additive petition. GRAS substances are exempt from the provisions of the Toxic Substance Control Act, so that data on safety and environmental concerns developed by the petitioner for a GRAS affirmation petition need not be duplicated.

5. There is no known way to minimize the burdens on a small business wishing to petition for a GRAS regulation. The Agency has established criteria as to the type of data necessary for review of the safety of a GRAS ingredient. Where possible, assistance is given (in fact, a significant percentage of agency time is spent in assistance activities), but the Agency does not have the resources to do a firm's analytical studies or the animal feeding studies necessary for the evaluation of a new food ingredient.

6. GRAS petitions are submitted voluntarily to FDA for affirmation of a new food ingredient or to expand the usage of a currently regulated food ingredient. Reduced petitioning would lower the number of food ingredients being affirmed as GRAS. Also, as noted in item 3, if a notification procedure is implemented, petitions for affirmation of GRAS status would be discontinued.

7. Data collection for GRAS affirmation petitions is consistent with all requirements of 5 CFR 1320.5. While paragraph (h) states that all practicable steps should be taken to develop separate procedures for small business, there is no known method of providing separate and simplified procedures by which the safety of new food ingredients may be evaluated.

8. In accordance with 5 CFR 1320.8(d), on Wednesday, July 5, 2000 (65 FR 41472), a 60-day notice for public comment was published in the Federal Register. No comments were received from the public.

FDA meets regularly with petitioners in pre-petition discussions to ensure that data collected are those necessary and sufficient to reach a decision on a petition. The purpose of these consultations is to offer guidance on specific testing requirements for a new additive or a new use of a previously regulated additive. Any unresolved issues are usually the subject of a future consultation. Any policy issues would be referred to FDA management for consideration.

In general, the public sector has no involvement with data developed for GRAS affirmation petitions. Public opportunity for comment on a GRAS substance is given at the time a filing notice is published in the Federal Register and the public may, within 60 days of the publication of said notice, submit comments. All information in a GRAS affirmation petition is made

available for public disclosure.

9. No payment or gift is provided to respondents.

10. GRAS petitions cannot contain privileged information that is necessary to make a safety determination as all information is made available for public disclosure.

11. There are no questions of a sensitive nature in GRAS affirmation petition requirements.

12. FDA estimates the burden of this collection of information as follows:

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Table 1. -- Estimated Annual Reporting Burden[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 170.36(c)(1) | 1 | 1 | 1 | 2,614 (average) | 2,614 |

[1](Footnote) There are no capital costs or operating and maintenance costs associated with this collection of information.

**FDA estimates that it may receive one GRAS petition annually.Although the burden varies with the type, size, and complexity of the petition submitted, GRAS petitions may involve analytical work, analysis of appropriate toxicological studies, and the work of drafting the petition itself. Since 1980, FDA has not received any petitions for affirmation of GRAS status under 21 CFR part 186--Indirect Food Substances Affirmed As Generally Recognized As Safe. Section 184.1(a)(21 CFR 184.1(a)) affirms the use of those substances affirmed as GRAS in 21 CFR part 184--Direct Food Substances Affirmed As Generally Recognized As Safe, for use as indirect food ingredients.**

The agency was unable to obtain real data on annualized costs for respondents of GRAS affirmation petitions. However, the agency estimates that these costs are comparable to those costs associated with food additive petitions for which data were obtained. Calculation of the annualized costs to industry was done by soliciting information from Ciba-Geigy, SPI, Borg-Warner and Dow Chemical Co. On the costs of petitioning for a food additive. Assuming that the aggregate professional hourly cost is $50, then the cost for submitting a simple GRAS affirmation petition is $13,500 (calculated by multiplying the hourly cost and the total hours, $50 X 270 hours).

The following summaries list the annualized costs for the GRAS affirmation petitions received in fiscal year 1995 assuming an aggregate professional hourly cost of $50.

| | | | |
|---|---|---|---|
| (1) Simple GRAS petition: | 1 petition | 270 hours | $ 13,500 |
| (2) Average GRAS petition: | 3 petitions | 8400 hours | $420,000 |
| (3) Complicated GRAS petition: | 1 petition | 4400 | $220,000 |
| Total | 5 petitions | 13,070 | $653,500 |

13. There are no capital costs and or operating and maintenance costs associated with this collection of information.

14. Cost to Federal Government
The Food and Drug Administration reported approximately 4 person-years of professional time in the review of GRAS petitions in fiscal year 1995. Based on an average cost of approximately $180,000 per fully supported position (GS-12, step 2) per year, the cost of processing GRAS petitions is $720,000 per year (4 person-years X $180,000 = $720,000).

15. In the Federal Register of April 17, 1997 (62 FR 18938) FDA proposed to replace the current GRAS affirmation process with a notification procedure whereby any person may notify FDA of a determination that a particular use of a substance is GRAS. The petition would be a letter to FDA rather than a Federal Register notice. Since there have been no petitions received since 1997, FDA assigns minimal burden to this information collection until the rule is finalized within the next fiscal year.
16. No comprehensive tabulation of the data is planned or anticipated.

17. No approval is being sought to not display the expiration date for OMB approval of the information collection.

18. There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.